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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,201	04/25/2001	Susan Salceda	DEX-0196	2155

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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,201	SALCEDA ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following 240 inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-20, claim(s) 1, 7, drawn to a method for diagnosis the presence of prostate cancer, comprising determining the level of a cancer specific gene or CSG of SEQ ID Nos: 1-20. A method determining the level of a single CSG from SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 21-40, claims 1, 7, drawn to a method for diagnosis the presence of prostate cancer, comprising determining the level of a cancer specific gene product, encoded by SEQ ID Nos: 1-20. A method determining the level of a single CSG product encoded by SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 41-60, claim(s) 2, 4, 7, drawn to a method for diagnosis the presence of metastasis of prostate or monitoring onset of metastasis, comprising determining the level of a cancer specific gene or CSG of SEQ ID Nos: 1-20. A method determining the level of a single CSG from SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 61-80, claims 2, 4, 7, drawn to a method for diagnosis the presence of metastasis of prostate or monitoring onset of metastasis, comprising determining the level of a cancer specific gene product encoded by SEQ ID Nos: 1-20. A method determining the level of a single CSG product encoded by SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 81-100, claims 3, 5, 7, drawn to a method for staging prostate cancer, or monitoring changes in stages of prostate cancer, comprising determining the level of a cancer specific gene or CSG of SEQ ID Nos: 1-20. A method determining the level of a single CSG from SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 101-120, claims 3, 5, 7, drawn to a method for staging prostate cancer, or monitoring changes in stages of prostate cancer, comprising determining the level of a cancer specific gene product encoded by SEQ ID Nos: 1-20. A method determining the level of a single CSG product encoded by SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 121-140, claims 6, 7, drawn to a method for identifying therapeutic agents, comprising screening for molecules that bind to a cancer specific gene or CSG of SEQ ID Nos: 1-20. Each method using a single CSG from SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 141-160, claims 6, 7, drawn to a method for identifying therapeutic agents, comprising screening for molecules that bind to a cancer specific gene product encoded by SEQ ID Nos: 1-20. Each method using a single CSG product encoded by SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 161-180, claim 8, drawn to antibody which specifically binds to a cancer specific gene product encoded by SEQ ID Nos: 1-20. Each antibody specific for a single CSG product encoded by SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 181-200, claims 9, 10, drawn to a method of imaging prostate cancer, comprising administering an antibody which specifically binds to a cancer specific gene product encoded by SEQ ID Nos: 1-20. A method using each antibody specific for a single CSG product encoded by SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 201-220, claim 11, drawn to a method of treating prostate cancer, comprising administering an antibody which specifically binds to a cancer specific gene product encoded by SEQ ID Nos: 1-20. A method using each antibody specific for a single CSG product encoded by SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

Groups 221-240, claim 12, drawn to a method of treating prostate cancer, comprising administering an antibody conjugated to a cytotoxic agent, which specifically binds to a cancer specific gene product encoded by SEQ ID Nos: 1-20. A method using each antibody specific for a single CSG product encoded by SEQ ID Nos: 1-20 constitutes a single invention, and **not a species**.

In addition, upon the election of groups 1-120, further election of the following patentably distinct species of the claimed invention is required:

1) cells or tissues, and 2) bodily fluids.

Upon the election of groups 41-80, further election of the following patentably distinct species of the claimed invention is required:

Metastasis or onset of metastasis.

Upon the election of groups 81-100, further election of the following patentably distinct species of the claimed invention is required:

Staging prostate cancer or monitoring changes in stages of prostate cancer.

Upon the election of groups 121-160, further election of the following patentably distinct species of the claimed invention is required:

Imaging or treating prostate cancer.

Upon the election of groups 181-200, further election of the following patentably distinct species of the claimed invention is required:

Paramagnetic ions or a radioisotope.

The inventions are distinct, each from each other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group 1, claims 1, 7, forms a single general inventive concept of a method for diagnosis prostate cancer, comprising determining the level of the polynucleotide of SEQ ID NO:1..

Groups 2-160, 181-240 are additional methods, using sequences that are structurally distinct from SEQ ID NO:1 or having different objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success. Further, the methods of groups (1-40) and (41-80) are distinct, because detection of prostate cancer does not mean that metastatic prostate cancer is detected.

Groups 161-180 are drawn to antibodies to different gene products encoded by SEQ ID Nos: 1-20, which are different from the method claims of group 1

The species cells or tissues and bodily fluids are distinct, because detection of a gene or gene product in protate cells does not mean that said gene or gene product is detected in bodily fluid, because not any gene or gene product is secreted from the cells or tissues.

The species detection of metastasis and onset of metastasis are distinct, because they have different objectives, schedules used, response variables and criteria for success.

The species staging prostate cancer or detection in changes in stages of prostate cancer are distinct, because they have different objectives, schedules used, response variables and criteria for success.

The species imaging or treating cancer are distinct, because they have different objectives, schedules used, response variables and criteria for success.

The species paramagnetic ions and a radioisotope are distinct because they are structurally distinct.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

June 15, 2002

SUSAN UNGAR, PH.D
PRIMARY EXAMINER